

APPLICATION
OF
DAVID A. FERRERA
FOR
UNITED STATES LETTERS PATENT
ON
COMPOSITE GUIDEWIRE

Client ID/Matter No. MICRU:64958

Sheets of Drawing: ONE (1)

Express Mail Label No. EV 327059590 US

Customer No. 24201

Attorneys
FULWIDER PATTON LEE & UTECHT, LLP
Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045

COMPOSITE GUIDEWIRE

BACKGROUND OF THE INVENTION

Field of the Invention:

This invention relates generally to vascular interventional medical devices, and more particularly concerns guide wires for use in a therapeutic system or for delivery of medical devices.

5 Description of Related Art:

Conventional minimally invasive catheter based therapies typically require guidewires that are one to two meters long extending through a longitudinal lumen in the catheter, and that are torqueable and pushable at the proximal end, yet
10 soft and flexible at the distal end. Many such guidewires are made of stainless steel or the like, and are ground to tapers which provide the desired bending properties along the guidewire. It is useful for such guidewires to be torqueable from the base of the guidewire for manipulation of the distal tip, which is typically bent, for guiding the distal tip through vascular passages. While such guidewires need to be torqueable,
15 pushable and resilient, particularly at the proximal regions of the guidewire, they also need to be flexible, particularly at the distal regions of the guidewire.

One prior guidewire for use with a catheter includes a core wire formed from a nickel titanium alloy, with a tapered distal tip portion and a distal end cap, covered by a sheath of material such as polyurethane, polyethylene, nylon, silicone,
20 polytetrafluoroethylene, cellulose, starch or gelatin. Another prior guidewire comprises a composite guidewire with a core of stainless steel or a nickel titanium alloy, a tapered distal region ending in a distal flexible coil and end cap, also having a major portion of the guidewire covered by a thin layer of polymeric material, such as polysulfones, polyfluorocarbons, polyolefins, polyesters, polyamides,

polyurethanes, blends and copolymers such as polyether block amides.

However, there remains a need for a guidewire with enhanced proximal stiffness, with a stiff, high modulus reinforcement, allowing for greater manipulation of the guidewire by the physician, along with greater distal tip flexibility with radiopacity. The present invention meets these needs.

SUMMARY OF THE INVENTION

Briefly, and in general terms, the present invention provides an improved composite guidewire with a proximal high modulus reinforcement member for promoting greater proximal stiffness, with a tapered distal region and distal radiopaque coil providing greater distal tip flexibility with radiopacity. The composite structure thus advantageously provides for a composite guidewire with greater resilience, a transition in stiffness, and tip flexibility. The proximal stiffer, high modulus member, covering or reinforcing a nickel alloy core, can be formed of high modulus metals such as stainless steel, titanium, and the like, allowing for greater manipulation of the guidewire by the physician, while the distal coil has enhanced durability, being formed from a composite strand of a nickel titanium alloy and platinum.

The present invention accordingly provides for a composite guidewire having an elongated, flexible core formed from a nickel titanium alloy having proximal and distal regions, with the distal region having a tapered portion, a reinforcement tube disposed over the proximal region of the core, a primary coil disposed over the tapered distal region of the core, with a coating of a heat shrinkable material disposed over at least a portion of the reinforcement member, an intermediate portion of the core, and at least a portion of the primary coil, and a distal tip secured to the distal end of the core.

In a presently preferred embodiment, the core is a nickel titanium alloy rod, although the core may alternatively be formed of one or more elongated strands of nickel titanium alloy, or an elongated tube. In another presently preferred aspect,

the proximal reinforcement member is formed as an elongated ground stainless steel hypo tube, although the reinforcement member may alternatively be formed of an elongated tube made of titanium, or a nickel titanium alloy. In another presently preferred aspect, the proximal reinforcement member is formed with a distal tapered portion, to provide for a transition in stiffness of the guidewire. In a presently preferred embodiment, the heat shrinkable coating is formed from an elongated tube of polytetrafluoroethylene (PTFE), although the heat shrinkable coating may also be selected from other heat shrinkable materials such as polyethylene, for example. In another presently preferred aspect of the invention, the distal primary coil is formed from one or more nickel titanium alloy strands or wires, and in another presently preferred aspect the distal primary coil is formed from one or more platinum wires, or a combination of one or more nickel titanium alloy strands and one or more platinum wires. In one currently preferred embodiment, the distal tip is formed of platinum, and is bonded to the distal end of the core such as by welding, or soldering, or the like, although the distal tip may also be formed of other materials such as a tantalum filled epoxy adhesively bonded to the distal end of the core.

These and other aspects and advantages of the invention will become apparent from the following detailed description and the accompanying drawings, which illustrate by way of example the features of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a longitudinal sectional schematic diagram of the composite guidewire of the invention;

Fig. 2 is a transverse sectional view taken along line 2-2 of Figure 1;

Fig. 3 is a transverse sectional view similar to Fig. 2 illustrating a first alternate preferred embodiment;

Fig. 4 is a transverse sectional view similar to Fig. 2 illustrating a second alternate preferred embodiment;

Fig. 5 is a transverse sectional view taken along line 5-5 of Figure 1;

Fig. 6 is a transverse sectional view taken along line 6-6 of Figure 1;

Fig. 7 is a transverse sectional view taken along line 7-7 of Figure 1;

Fig. 8 is a transverse sectional view taken along line 8-8 of Figure 1;

5 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Guidewires used for vascular therapeutic intervention typically need to be torqueable, pushable and resilient over a proximal region of the guidewire, and flexible, over the distal region of the guidewire. While tapered guidewires can provide a range of proximal stiffness and torqueability to distal flexibility, enhancement of the proximal stiffness of such guidewires can give a physician manipulating the guidewire better control over the distal positioning of the guidewire.

As is illustrated in the drawings, the invention is embodied in a composite guidewire 10 illustrated in Figure 1, having a central elongated, flexible core 12 preferably formed from a nickel titanium alloy such as Nitinol, having a proximal region 14 and a distal region 16. The distal region of the core preferably includes a tapered portion 18, to provide for a gradual transition to increased flexibility in the distal region of the guidewire. The core is preferably formed as an elongated rod, as illustrated in Fig. 2, although the core may also be formed of a one or more strands 20 of a nickel titanium alloy such as Nitinol as shown in Fig. 3. The one or more strands may be helically wound, or may run longitudinally parallel along the length of the guidewire. Alternatively, the core may also be formed from an elongated tube 22 such as a hypo tube made of a nickel titanium alloy such as Nitinol, as shown in Fig. 4.

A proximal reinforcement tube 24 is preferably disposed over the proximal region of the core, with the reinforcement tube preferably having a tapered distal portion 26, to provide for a transition in stiffness of the guidewire. The proximal reinforcement member is currently preferably formed from an elongated ground stainless steel hypo tube, although the reinforcement member may alternatively be formed of an elongated tube made of titanium, or a nickel titanium

alloy such as Nitinol.

A primary coil 28 is preferably bonded over the tapered distal region of the core, such as by welding, solder, or by adhesive such as cyanoacrylate. The primary coil is currently preferably formed from one or more nickel titanium alloy strands or wires as described above, one or more platinum wires to provide radiopacity to the primary coil, or a combination of one or more nickel titanium alloy strands and one or more platinum wires. A distal tip 30 is preferably secured to the distal end 32 of the core and to the distal end 32 of the primary coil. In one currently preferred embodiment, the distal tip is formed of platinum, and is bonded to the distal end of the core such as by welding, or soldering, or the like, although the distal tip may also be formed of other materials such as a tantalum filled epoxy adhesively bonded to the distal end of the core and to the distal end of the primary coil.

An outer coating of a heat shrinkable polymeric material 34, such as an elongated tube of polytetrafluoroethylene (PTFE), is also preferably disposed over at least a distal portion of the reinforcement member 36, an intermediate portion 38 of the core, and at least a portion 40 of the distal primary coil. The heat shrinkable coating may also be selected from other similar suitable heat shrinkable materials such as polyethylene, for example.

It will be apparent from the foregoing that while particular forms of the invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.